

**AMENDMENTS TO THE CLAIMS:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

1-19 (cancelled).

20 (currently amended). A kit of parts comprising:

(a) a pharmaceutical formulation including a low molecular weight thrombin inhibitor, or a ~~pharmaceutically acceptable derivative thereof~~ salt, solvate or a pharmaceutically acceptable derivative, said derivative having the inhibitory activity against thrombin, in admixture with a pharmaceutically acceptable adjuvant, diluent or carrier; and

(b) a pharmaceutical formulation including a prodrug of the low molecular weight thrombin inhibitor of formulation (a), or a pharmaceutically acceptable ~~derivative~~ salt or solvate of that prodrug, in admixture with a pharmaceutically acceptable adjuvant, diluent or carrier,

which formulations (a) and (b) are each provided in a form that is suitable for administration in conjunction with the other.

21 (cancelled).

22 (currently amended). The kit of parts as claimed in Claim 20, wherein formulations (a) and (b) are suitable for sequential, ~~separate~~ or simultaneous use in the treatment of a condition in which inhibition of thrombin is required or desired.

23 (previously presented). The kit of parts as claimed in Claim 22, wherein the condition is deep venous thrombosis.

24 (previously presented). The kit of parts as claimed in Claim 20, wherein the thrombin inhibitor is melagatran.

25 (previously presented). The kit of parts as claimed in Claim 24, wherein the prodrug is of the formula



wherein  $R^1$  represents linear or branched  $C_{1-6}$  alkyl and the OH group replaces one of the amidino hydrogens in Pab.

26 (previously presented). The kit of parts as claimed in Claim 25, wherein  $R^1$  represents methyl, ethyl or propyl.

27 (previously presented). The kit of parts as claimed in Claim 25, wherein  $R^1$  represents ethyl.

28 (currently amended). The kit of parts as claimed in Claim 20, 24 or 27,  
wherein the formulation comprising thrombin inhibitor, or ~~derivative thereof~~ salt, solvate

or a pharmaceutically acceptable derivative, said derivative having the inhibitory activity against thrombin, is a parenteral formulation and that comprising the prodrug, or ~~derivative thereof~~ salt or solvate of said prodrug, is an oral formulation.

29 (previously presented). A method of making the kit of parts as defined in Claim 20, 24 or 27, which method comprises bringing a formulation (a) into association with a formulation (b), thus rendering the two formulations suitable for administration in conjunction with each other.

30 (previously presented). The kit of parts comprising:

(1) one of formulations (a) and (b) as defined in Claim 20, 24 or 27;

together with

(2) instructions to use said one formulation in conjunction with the other of the two formulations (a) and (b).

31 (currently amended). A pharmaceutical formulation including:

(i) a low molecular weight thrombin inhibitor ~~(or a pharmaceutically acceptable derivative thereof)~~ or a salt, solvate or a pharmaceutically acceptable derivative, said derivative having the inhibitory activity against thrombin; and

(ii) a prodrug of the low molecular weight thrombin inhibitor component (i) ~~(or a pharmaceutically acceptable derivative of that prodrug)~~ or a pharmaceutically acceptable salt or solvate of that prodrug, in admixture with

(iii) a pharmaceutically acceptable adjuvant, diluent or carrier.

32 (currently amended). A method of treatment of a condition in which inhibition of thrombin is required or desired, which comprises administration of:

(a) a pharmaceutical formulation including a low molecular weight thrombin inhibitor, or a ~~pharmaceutically acceptable derivative thereof~~ salt, solvate or a pharmaceutically acceptable derivative, said derivative having the inhibitory activity against thrombin, in admixture with a pharmaceutically acceptable adjuvant, diluent or carrier; in conjunction with

(b) a pharmaceutical formulation including a prodrug of the low molecular weight thrombin inhibitor of formulation (a), or a pharmaceutically acceptable ~~derivative~~ salt or solvate of that prodrug, in admixture with a pharmaceutically acceptable adjuvant, diluent or carrier,

to a patient suffering from, or susceptible to, such a condition in an effective amount and for a time and under conditions suitable for reducing the incidence of said condition.

33 (previously presented). The method as claimed in Claim 32 in which the formulation (a) is administered prior to commencement of administration of formulation (b).

34 (previously presented). A method of treatment of a condition in which inhibition of thrombin is required or desired, which comprises administration of a formulation as defined in Claim 31 to a patient suffering from, or susceptible to, such a

condition in an effective amount and for a time and under conditions suitable for reducing the incidence of said condition.

35 (previously presented). The method as claimed in Claim 32, wherein the condition is deep venous thrombosis.

36 (previously presented). The method as claimed in Claim 35, wherein the thrombosis results from surgery.

37 (previously presented). The method as claimed in Claim 36, wherein the surgery is gastrointestinal surgery or orthopedic surgery.

38 (previously presented). The method as claimed in Claim 36, wherein formulation (a) is administered parenterally prior to or after surgery and formulation (b) is administered orally following that surgery.

39 (previously presented). The method as claimed in Claim 36, wherein formulation (a) is administered parenterally prior to and after surgery and formulation (b) is administered orally following that surgery.

40 (previously presented). The method as claimed in Claim 32, 35, 36, 37, 38 or 39, wherein the thrombin inhibitor is melagatran.

41 (currently amended). A method of treatment of a condition in which inhibition of thrombin is required or desired, which comprises administration of:

(a) a pharmaceutical formulation including melagatran, or a ~~pharmaceutically acceptable derivative thereof~~ salt, solvate or a pharmaceutically acceptable derivative, said derivative having the inhibitory activity against thrombin, in admixture with a pharmaceutically acceptable adjuvant, diluent or carrier; in conjunction with

(b) a pharmaceutical formulation including a prodrug of formula



wherein  $R^1$  represents linear or branched  $C_{1-6}$  alkyl and the OH group replaces one of the amidino hydrogens in Pab, or a pharmaceutically acceptable ~~derivative~~ salt or solvate of that prodrug, in admixture with a pharmaceutically acceptable adjuvant, diluent or carrier,

to a patient suffering from, or susceptible to, such a condition in an effective amount and for a time and under conditions suitable for reducing the incidence of said condition.

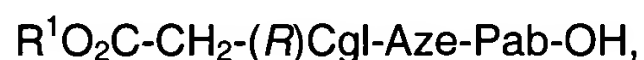
42 (previously presented). The method as claimed in Claim 41, wherein  $R^1$  represents methyl, ethyl or propyl.

43 (previously presented). The method as claimed in Claim 41, wherein  $R^1$  represents ethyl.

44-45 (cancelled).

46 (previously presented). The pharmaceutical formulation as claimed in Claim 31 wherein the thrombin inhibitor is melagatran.

47 (previously presented). The pharmaceutical formulation as claimed in Claim 46 wherein the prodrug is of the formula



wherein  $R^1$  represents linear or branched  $C_{1-6}$  alkyl and the OH group replaces one of the amidino hydrogens in Pab.

48 (previously presented). The pharmaceutical formulation as claimed in Claim 47 wherein  $R^1$  represents methyl, ethyl, or propyl.

49 (previously presented). The pharmaceutical formulation as claimed in Claim 47 wherein  $R^1$  represents ethyl.

50 (cancelled).

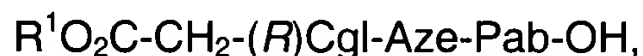
51 (previously presented). The method as claimed in Claim 34 wherein the condition is deep venous thrombosis.

52 (previously presented). The method as claimed in Claim 51 wherein the thrombosis results from surgery.

53 (previously presented). The method as claimed in Claim 52 wherein the surgery is gastrointestinal surgery or orthopedic surgery.

54 (previously presented). The method as claimed in Claim 34 wherein the thrombin inhibitor is melagatran.

55 (previously presented). The method according to Claim 34 wherein the thrombin inhibitor is melagatran, and the prodrug is of formula



wherein  $R^1$  represents linear or branched  $C_{1-6}$  alkyl and the OH group replaces one of the amino hydrogens in Pab.

56 (previously presented). The method as claimed in Claim 55, wherein  $R^1$  represents methyl, ethyl or propyl.

57 (previously presented). The method as claimed in Claim 55, wherein  $R^1$  represents ethyl.